

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001440

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: C12N 7/00, C07K 14/02, C12Q 1/70

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPIDS, CA, MEDLINE (HEPATITIS B, HBV, VARIANT, RESISTANT, MUTANT, NUCLEOSIDE ANALOG, FTC, ADV, LMV, TFV, POLYMERASE, RESIST)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/087351 A1 (MELBOURNE HEALTH) Published 23 October 2003. (Whole document)	1-18, 21, 22, 27-44, 47, 48, 53-55, 58, 59, 64-66, 69, 70, 75-77, 80, 81, 88-92, 95, 96, 101-104, 107, 108, 113-116; 119, 120 and 125-130

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
3 December 2004Date of mailing of the international search report  
20 DEC 2004Name and mailing address of the ISA/AU  
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/066841 A1 (MELBOURNE HEALTH) Published 14 August 2003. (Whole document)	1, 3, 17, 18, 21, 22, 25-27, 29, 43, 44, 47, 48, 51-55, 58, 59, 62-66, 69, 70, 73-77, 80- 83, 86-92, 95, 96, 99-104, 107, 108, 111, 112, and 125- 130
PX	WO 2004/031224 A2 (GILEAD SCIENCES, INC.) Published 15 April 2004 (Page 2, line 22; Page 3, lines 4-11; Page 5 lines 20-23; Claims 1-3, 18, 19)	1-3, 17, 18, 21, 27-29, 43, 44 and 47
X	WO 2000/061758 A1 (NORTH WESTERN HEALTH CARE NETWORK) Published 19 October 2000 (Page 19, line 28; Pages 33, line 33- page 35, Claims 31-33)	1, 3, 101, 104, 106, 108 and 112
X	Torresi. J., et al; "Restoration of Replication Phenotype of Lamivudine-Resistant Hepatitis B Virus Mutants by Compensatory Changes in the "Fingers" Subdomain of the Viral Polymerase Selected as a Consequence of Mutations in the Overlapping S Gene". Virology (2002); Vol 299: 88-99. (Abstract; Page 89, col 1; Page 93, discussion to page 94, col 1, para 1)	1, 3, 21, 113 and 114
X	Ono. S. K., et al; "The polymerase L528M mutation cooperates with nucleotide binding-site mutations, increasing hepatitis B virus replication and drug resistance". Journal of Clinical Investigation (2001); Vol 107(4): 449-455. (Abstract; Page 449; Page 451, col 1, para 1; Page 452 col 2 last line to page 453, col 1, lines 1-5)	1, 3, 17, 21, 75, 76, 80 and 82

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**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 19, 45, 56, 67, 78, 93, 105 and 117 in part  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
Claims 19, 45, 56, 67, 78, 93, 105 and 117 are not clear, the claims refer to a number of mutations in the HBV DNA polymerase and one of them is rt180L. It is not clear what amino acid is mutated to L at position 180 of the reverse transcriptase part of the polymerase. As such, no comment is made on the novelty and inventive step of these claims, in so far as they relate to rt180L.
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

**PCT/AU2004/001440**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO	03087351	None			
WO	03066841	CA	2475446	EP	1476543
WO	04031224	None			
WO	0061758	AU	36480/00	EP	1169452
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					